COMPARATIVE STUDY OF EFFICACY OF LOCALIZATION AND FRAGMENTATION OF RENAL STONE BY USG AND FLUOROSCOPY GUIDED ESWL

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of the requirement for the degree of

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DECLARATION

I solemnly declare that this dissertation **"COMPARATIVE STUDY OF EFFICACY OF LOCALIZATION AND FRAGMENTATION OF RENAL STONE BY USG AND FLUOROSCOPY IN ESWL"** was proposed by me in the Department of Urology, Kilpauk Medical College and Govt. Royapettah Hospital, Chennai under the guidance and supervision of **Prof.K.THIYAGARAJAN, M.S.,M.Ch. (Urology), D.N.B (Urology)** Professor and Head of the Department of Urology, Kilpauk Medical College and Govt. Royapettah Hospital,Chennai and **Prof. V. SELVARAJ, M.S., M.Ch. (Urology),** Additional Professor, Department of Urology, Kilpauk Medical College,Chennai.

This Dissertation is submitted to the Tamilnadu Dr. M.G.R. Medical University, Chennai in partial fulfilment of the University requirements for the award of degree of M.Ch Genitourinary Surgery.

Place : Chennai
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BONAFIDE CERTIFICATE

This is to certify that this dissertation entitled **"COMPARATIVE STUDY OF EFFICACY OF LOCALIZATION AND FRAGMENTATION OF RENAL STONE BY USG AND FLUOROSCOPY IN ESWL"** submitted by **Dr.A.ARUNAGIRI,** appearing for **M.Ch (Urology)** degree examination in August 2010 is a bonafide record of work done by him, under my guidance and supervision in partial fulfilment of requirement of the Tamilnadu Dr. M.G.R. Medical University, Chennai. I forward this to the Tamilnadu Dr. M.G.R. Medical University, Chennai, Tamilnadu, India.

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CONTENTS

ABBREVATIONS

Age Group	1	-	< 25
	2	-	26 to 35
	3	-	36 to 45
	4	-	$\geq$ 46
Sex -	1	-	Male
	2	-	Female
Side -	R	-	Right
	L	-	Left
Location -	1	-	pelvis
	2	-	lower calyx
	3	-	middle calyx
	4	-	upper calyx
Stent	1	-	Done
	2	-	Not done
Composition	1	-	Mixed
	2	-	Uric acid
	3	-	Magnesium Ammonium Phosphate
Results	SF	-	Stone free
	CF	-	Completely fragmented
	RF	-	Residual fragment

INTRODUCTION

Prior to the introduction of extracorporeal shockwave lithotripsy (ESWL) in 1980, the only treatment available for calculi that could not pass through the urinary tract was open surgery. Since then, ESWL has become the preferred tool in the urologist's armamentarium for the treatment of renal stones, proximal stones, and midureteral stones. Compared with open and endoscopic procedures, ESWL is minimally invasive, exposes patients to less anaesthesia, and yields equivalent stone-free rates in appropriately selected patients.

The efficacy of ESWL lies in its ability to pulverize calculi in vivo into smaller fragments, which the body can then expulse spontaneously. Shockwaves are generated and then focused onto a point within the body. The shockwaves propagate through the body with negligible dissipation of energy (and therefore damage) owing to the minimal difference in density of the soft tissues. At the stone-fluid interface, the relatively large difference in density, coupled with the concentration of multiple shockwaves in a small area, produces a large dissipation of energy. Via various mechanisms, this energy is then able to overcome the tensile strength of the calculi, leading to fragmentation. Repetition of this process eventually leads to pulverization of the calculi into small fragments (ideally <1 mm) that the body can be passed spontaneously.

The lifetime prevalence of kidney stone disease is 1-15% with the probability of having a stone varying according to age, gender, race, and geographic location. Management of renal calculi has changed dramatically during the past 30 years.

Minimally invasive techniques especially the introduction and development of Extra Corporeal Shock Wave Lithotripsy (ESWL) virtually have replaced open surgical stone removal. ESWL was introduced by ***Christian Chaussay*** in 1980. 80-85% of simple renal calculi can be treated effectively with non invasive ESWL and won the Nobel prize.

ESWL is a non invasive therapy for urinary calculi with good success rates with decreased morbidity, length of hospitalization and anaesthesia requirement. According to AUA guidelines ESWL is the preferred modality of treatment for renal stones of < 2 cm in size.

Even large and complex renal calculi may be treated effectively with these minimally invasive techniques. For complete staghorn calculi a combined PCNL and ESWL (Sandwich) therapy have been recommended as the first line of treatment.

However even for the calculi of this size, the stone free rates vary between 66% - 99%. This variation in stone fragmentation is due to factors like size, stone location, chemical composition, BMI, other congenital anatomical anomalies, shock wave generator and presence of obstruction (or) infection.

The renal calyces are the most common location of asymptomatic (or) incidentally discovered urinary calculi. Pelvic calculi, upper calyceal and middle calyceal stones of less than 2cm have been treated with ESWL with stone free rate of upto 99%.

The management of lower calyceal stone is more controversial and in this situation stone free rate after ESWL range from 44-79% (4 & 5). Lower calyceal stone with favourable infundibulo pelvic anatomy have good success rate with ESWL.

Stone fragmentation by ESWL is variable. So it is desirable to reduce the number of retreatment (or) limit the therapy to one definite therapy. In addition, the local effects of ESWL upon renal parenchyma and surrounding organs are also of concern. The long term prevalence rate of HT and change in renal plasma flow following ESWL treatment constitute a further reason for the surgeon to limit the therapy to one definite treatment. The success of ESWL has been correlated with radiodensity of the renal stone on plain X-ray KUB. Overall accuracy of predicting calculi composition from plain radiographs was reported to be only 39% which is at present insufficient for clinical use.

The Emergence of Non Contrast CT KUB in the assessment of flank pain and the subsequent availability of the attenuation coefficient measurement has interacted several groups in comparing attenuation and stone composition *invitro.* These studies have determined that stone compositions can be predicted on the basis of the attenuation value determined by NCCT.

REVIEW OF LITERATURE

The prevalence of stone disease is very high in most parts of India because of its geography, dietary habits, temperature and humidity superimposed on their intrinsic factors predisposing to stone formation. Prevalence of stone disease ranges from 1-15% and varies by age, sex and race. For men incidence begins to rise after age 20, peaks between 40 and 60 years at about 3/1000/y and then begin to decline. For women incidence rates seem to be higher in late 20s (2.5/1000/y) and then decreasing to 1/1000/y age 50. The increased incidence and prevalence of stone disease in recent years, may be from increased detection of asymptomatic stones discovered with the greater use and higher sensitivity of imaging studies.

Stone disease can be easily diagnosed using imaging studies X-ray KUB, USG KUB and IVU, CT KUB. Plain radiography detects radio opaque calculi. The limitations are bowel gas, bone shadow overlapping and cannot detect radiolucent stones.

USG KUB can detect calculi in the renal area and associated obstruction and dilatation of pelvi calyceal system. The limitations in the images are obesity, bowel gas and ureteric calculi.

Non contrast CT KUB is a simple method to detect renal and ureteric calculi, assess stone burden with density, assess the stone number, stone location and dilatation of pelvicalyceal system.

Various treatment options which are non invasive and other minimally invasive surgeries have replaced the open stone surgery nowadays. Extra Corporeal Shockwave Lithotripsy is a non invasive treatment option with minimal morbidity.

The word Lithotriptor is of Greek origin and means stone crusher. Lithotriptors have evolved from many years of research in physics of flight. Researchers discovered that raindrops striking an air craft during supersonic flight created shockwaves that had disintegrating effects on solid materials. Refinements of these findings led to the intervention of the lithotriptor as a means for treating urinary calculi.

In February 1980 ***Dr. Christian Chaussay, University of Munich*** first used electrically generated focused shockwaves to fragment stones within a human kidney. The first experimental treatment began the era of ESWL. The first Lithotriptor model HM 1 soon replaced by HM 2 in 1982 and in 1984 by Model HM 3. Each new generation reflects progression of technology and a growing sophistication. Further modification of the generation is the consolidation of fluoroscopic screens and the lithotripsy control into a convenient, efficient and user friendly console. Shockwave lithotripsy technology has advanced rapidly in terms of shock wave generation, focusing, patient coupling and stone localization making it the most widely used treatment for renal calculi.

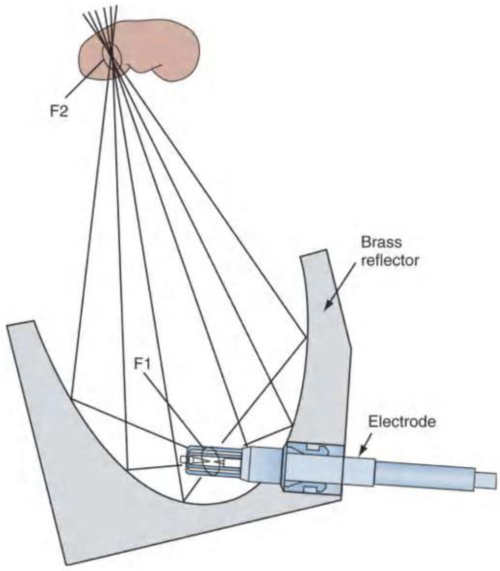
Methods of Shock Wave Generation

Lithotripters, are characterized by the type of shockwave generators they employ. Commercially available lithotripters use Electro hydraulic (EH), Electromagnetic (EM) and Piezoelectric generators .

Electro Hydraulic (Spark Gap) Generators

The original method of shockwave generation (used in the Dornier HM3) was electro hydraulic, meaning that the shockwave is produced via spark-gap technology. In an electro hydraulic generator, a high-voltage electrical current passes across a spark-gap electrode located within a water-filled container. The discharge of energy produces a vaporization bubble, which expands and immediately collapses, thus generating a high-energy pressure wave.

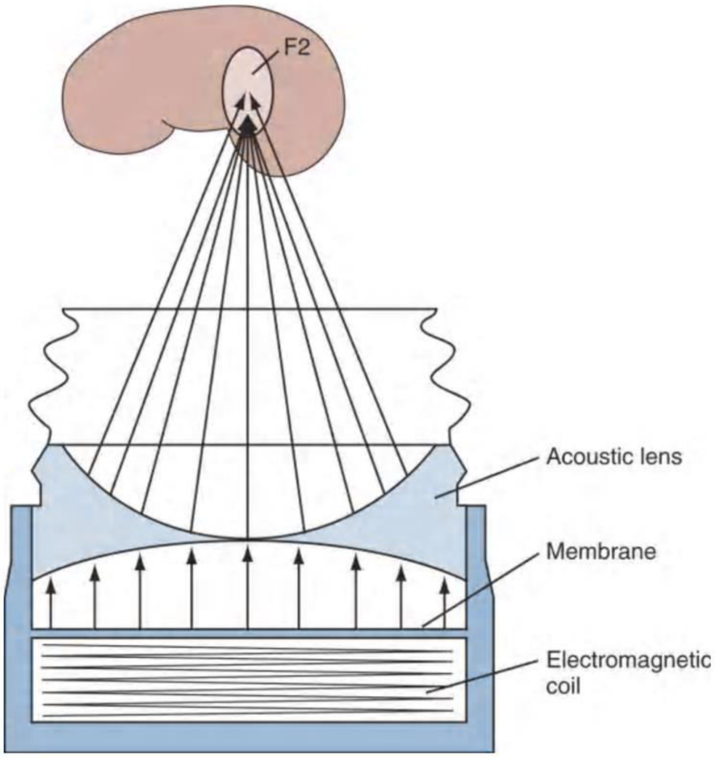
A spherically expanding shockwave is generated by an underwater spark discharge (15000-25000V) Electrode at F1 and focused by hemi ellipsoid reflector and focused on to calculus F2. Advantage of this generator is effectiveness in breaking kidney stones. Disadvantages are substantial pressure fluctuations from shock to shock and a relatively short electrode life.



Electromagnetic Generators

In an electromagnetic generator, a high voltage is applied to an electromagnetic coil, similar to the effect in a stereo loudspeaker. This coil, either directly or via a secondary coil, induces high-frequency vibration in an adjacent metallic membrane. This vibration is then transferred to a wave-propagating medium (ie, water) to produce shockwaves.

EMSE - Electromagnetic shock wave Emitter. The disk coil is charged with high voltage pulses (5000-20000V) whereby the membrane lying directly on the coil is thrust outwards. The shock wave generated is focused by means of an acoustic lens.



Advantages

Electromagnetic Generators are more controllable and reproducible. Introduction of energy into patients body over a large skin area cause less pain, small focus can be achieved with high energy densities which may increase its effectiveness is breaking stones.

Disadvantages

Small focal region of high energy reflects an increased rate of subcapsular hematoma formation.

Piezoelectric Generator

The piezoelectric effect produces electricity via application of mechanical stress. The Curie brothers first demonstrated this in 1880. The following year, Gabriel Lippman theorized the reversibility of this effect, which was later confirmed by the Curie brothers. The piezoelectric generator takes advantage of this effect. Piezoelectric ceramics or crystals, set in a water-filled container, are stimulated via high-frequency electrical pulses. The alternating stress/strain changes in the material create ultrasonic vibrations, resulting in the production of a shockwave.

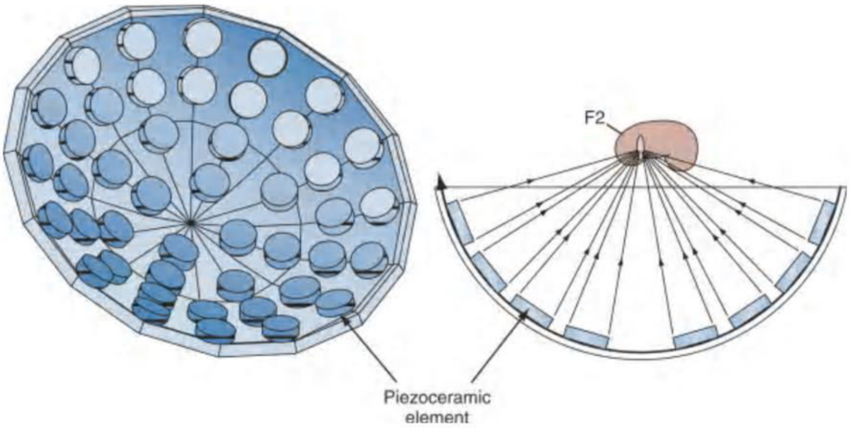
Piezoelectric energy source uses a spherical array of piezoelectric crystals excited by electric impulse 2000-6000V, by simultaneous sudden expansion, shockwaves are generated and focused.

Advantages

Focusing accuracy, a long service life, and anaesthesia free treatment.

Disadvantages

Insufficient power it delivers hampers its ability to effectively break renal stones.



Focusing systems

The focusing system is used to direct the generator-produced shockwaves at a focal volume in a synchronous fashion. The basic geometric principle used in most lithotripters is that of an ellipse. Shockwaves are created at one focal point (F1) and converge at the second focal point (F2). The target zone, or blast path, is the 3-dimensional area at F2, where the shockwaves are concentrated and fragmentation occurs.

Focusing systems differ, depending on the shockwave generator used. Electrohydraulic systems used the principle of the ellipse; a metal ellipsoid directs the energy created from the spark-gap electrode. In piezoelectric systems, ceramic crystals arranged within a hemispherical dish direct the produced energy toward a focal point. In electromagnetic systems, the shockwaves are focused with either an acoustic lens (Siemens system) or a cylindrical reflector (Storz system).

Shock wave focusing allows for the concentration of shockwave energy at a focal point. The focal area refers to the volume within which the shock waves are concentrated.

Coupling mechanisms

In the propagation and transmission of a wave, energy is lost at interfaces with differing densities. As such, a coupling system is needed to minimize the dissipation of energy of a shockwave as it traverses the skin surface. The usual medium used is water, as this has a density similar to that of soft tissue and is readily available. In first-generation lithotriptors (Dornier HM3), the patient was placed in a water bath. However, with second- and third-generation lithotriptors, small water-filled drums or cushions with a silicone membrane are used instead of large water baths to provide air-free contact with the patient's skin. This innovation facilitates the treatment of calculi in the kidney or the ureter, often with less anaesthesia than that required with the first-generation devices.

Shock waves can be coupled effectively into body by degassed water which has matched acoustic impedance to soft tissues. Current lithotripter use enclosed water cushion with a coupling medium of ultrasound gel instead of 1000 L water bath. Shock wave attenuation through the membrane of water cushion amounts to 20% loss of energy.

Localization systems

Imaging systems are used to localize the stone and to direct the shockwaves onto the calculus, as well as to track the progress of treatment and to make alterations as the stone fragments. The two methods commonly used to localize stones include fluoroscopy and ultrasonography.

Fluoroscopy, which is familiar to most urologists, involves ionizing radiation to visualize calculi. Disadvantages are Ionizing radiation to both the patient and medical staff, and it is not useful in localizing radiolucent calculi. As such, fluoroscopy is excellent for detecting and tracking calcified and otherwise radio-opaque stones, both in the kidney and the ureter. Conversely, it is usually poor for localizing radiolucent stones (eg, uric acid stones). To compensate for this shortcoming, intravenous contrast can be introduced or (more commonly) cannulation of the ureter with a catheter and retrograde instillation of contrast (ie retrograde pyelography) can be performed.

Ultrasonographic localization allows for visualization of both radio opaque and radiolucent renal stones and the real-time monitoring of lithotripsy. Most second-generation lithotripters can use this imaging modality, which is much less expensive to use than radiographic systems. Although ultrasonography has the advantage of preventing exposure to ionizing radiation, it is technically limited by its ability to visualize ureteral calculi, typically due to interposed air-filled intestinal loops. In particular, smaller stones may be easy to localize accurately.

Ultrasonography based lithotriptors offer the advantages of stone localization with continuous monitoring and can differentiate stent from stone in case of Renal calculus with stent.

USG COMPATIBLE ESWL

FLUOROSCOPY COMPATIBLE ESWL

History of the Procedure

Evolution of shockwave lithotriptors

The Dornier HM3, originally designed to test supersonic aircraft parts, was the first shockwave lithotripter introduced in the United States. Despite being somewhat out dated, it is still one of the most effective lithotripters and has become the standard to which other devices are compared. The design of the HM3 is based on an electrohydraulic shockwave generator; the shockwaves are focused via an ellipsoid metal water-filled tub in which both the patient and the generator are submerged. Biplanar fluoroscopy is used for localization, allowing placement of the calculi to be fragmented in the target zone.

Second-generation lithotripters typically use piezoelectric or electromagnetic generators as the energy source. When coupled with the appropriate focusing device, these shockwave generators commonly have a smaller focal zone. Although a smaller focal zone may minimize damage to the surrounding tissue, this comes at a price. During respiratory excursion, the stone may move in and out of the focal zone; this may compromise fragmentation rates. The coupling device in a second-generation lithotripter is a silicone-encased water cushion that coapts to the patient, a design that greatly simplifies the positioning of patients.

The new generation lithotripters have been designed to offer greater portability and adaptability. These systems often provide imaging with both fluoroscopy and ultrasonography. The ability to alternate between imaging modalities allows the urologist to compensate for the deficiencies of either system.

Most current lithotripters are powered by an electromagnetic generator. Electromagnetic generators and their focusing units are capable of delivering shockwaves that are similar in intensity to those of the HM3, but usually to a smaller focal zone. As mentioned above, this has the theoretical advantage of minimizing damage to surrounding soft tissue. However, because of the smaller focal zone, respiration may cause the stone to move out of the target zone for portions of the treatment. Although improved localization techniques and anesthetic manipulation can be used to account for this, the shockwaves applied while the stones are out of the target zone do not cause fragmentation. Thus, certain second and third-generation machines are associated with higher failure rates, incomplete treatment and the need for retreatment.

Pathophysiology

A stone is fragmented when the force of the shockwaves overcomes the tensile strength of the stone. Although incompletely understood, fragmentation is thought to occur through a combination of methods, including compressive and tensile forces, erosion, shearing, spalling, and cavitation. Of these various forces, the generation of compressive and tensile forces and cavitation are thought to be the most important.

When a shockwave is propagated through a medium (water), it loses very little energy until it crosses into a medium with a different density. If the medium is denser, compressive forces are produced on the new medium. Similarly, if the new medium is less dense, tensile stress is produced on the first medium. Upon hitting the anterior surface of a stone, the change in density creates compressive forces, causing fragmentation. As the wave proceeds through the stone to the posterior surface, the change from high to low density reflects part of the shockwave's energy, producing tensile forces, which again disrupt and fragment the stone.

In cavitation, shockwave energy applied at a focal point leads to failure of the liquid with generation of water-vapor bubbles. These gaseous bubbles collapse explosively, creating microjets that fracture and erode the calculus. This process can be monitored with real-time ultrasonography during the treatment and appears as swirling fragments and liquid in the focal zone.

Physical properties of renal calculi and tissue

Knowledge of acoustic and mechanical properties of renal calculi and tissue is important to understand shockwave – stone tissue interaction and the mechanisms of stone fragmentation and tissue injury during ESWL Acoustic properties determine the characteristics of shock wave propagation inside the stone and tissue materials as well as the wave transmission and reflection, at the stone tissue boundary. Mechanical properties dictate the response of the stone and tissue materials to shock wave loadings. Acoustic and mechanical properties of renal calculi depend primarily on the composition of stone.

Composition and structural features of renal calculi

The constituents of renal calculi are crystalline (95%) and non crystalline matrix materials (Protein, Cellular debris and organic materials)

Major crystalline components are calcium oxalate (Monohydrate and dihydrate) phosphates (hydroxyapatite, carbonate apatite struvite) uric acid, urate, cystine and xanthine. Renal calculi appear in wide range of shapes, sizes, colors and textures.

Acoustic properties of renal calculi and renal tissue

Acoustic properties are density, wave speed and acoustic impedance. Longitudinal wave propagation (compressional) characterized by parallel movements of material particles along the wave path. Transverse (Shear) wave propagation material particles move perpendicularly to wave path.

Calcium oxalate monohydrate and cystine stones have higher acoustic impedance. Stones with higher acoustic impedance would produce a stronger reflection of the shock wave at the anterior surface of stone resulting in less of the shock wave energy being transmitted into the stone to cause fragmentation.

Mechanical properties of renal calculi

Dynamic elastic properties of renal calculi depends upon resistance of stone material to elongation (or) shortening, shear deformation and volume change. Most renal calculi are brittle while cystine stones are ductile (more energy is needed to produce fracture) so most difficult to fragment during SWL.

Mechanisms of varying stone fragility

Stone fragility determines the response of a renal calculus to SWL therapy varies with composition, size, structural features of stone.

It has been reported that stone with homogenous structure are less fragile than stones with heterogenous structure. Most renal calculi are found to be brittle except cystine stones which are ductile. Elastic module determine a stones resistance to shock wave induced deformation, hardness determine a stone’s resistance to cavitation, microjet impact and fracture toughness determines a stone’s resistance to spalling damage and crack propagation. COM(Calcium oxalate monohydrate) and brushite stones are less fragile than MAP(Magnesium ammonium phosphates) and CA(Carboxy apatite) stones because COM and brushite stones are stiffer, harder and more resistant to fracture.

Modes of stone fragmentation

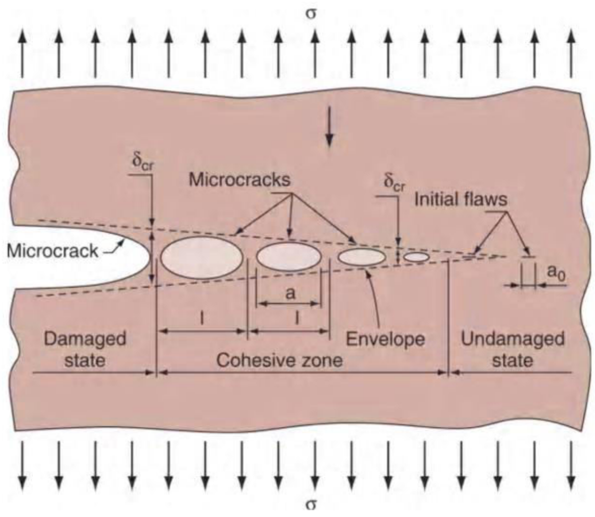
Stone fragmentation vary depending on composition, size and structural features.

Damage methods are surface erosion at the anterior surface of stone, spalling damage at the posterior surface of stone and layer separation at the interface of adjacent stone laminar surface.

Shock waves produce bubbles 100-200 μs size collapse rapidly near the stone surface, produce high speed microjet (770 m/s) impinge towards the stone surface to cause damage.

Anterior surface of stone numerous minute pits are formed and characteristic of cavitation induced surface erosion.

Spalling damage a separation of spherical cap from posterior surface of stone produced by reflected tensile waves. This mode of stone damage can be attributed to the reflected tensile waves generated at the layer interface because of acoustic impedance mismatch between stone crystalline and surrounding matrix materials. Numerous micro fracture grow and propagate to form large crack lines leading to stone disintegration.

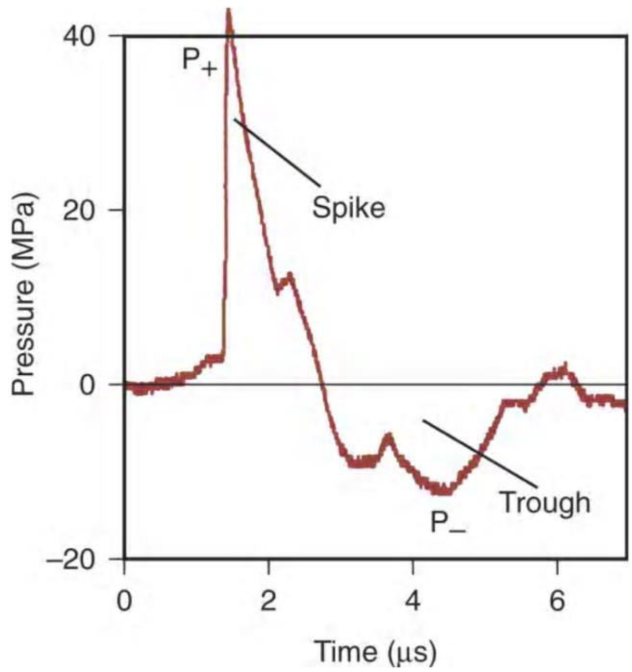


The ultimate goal of ESWL is to fragment renal and ureteric calculi as effectively as possible with minimizing the potential injury to surrounding tissues.

Mechanisms of stone fragmentation

Calculi maintain their form because of innate comprehensive forces. Fragmentation occurs when tensile strength of a calculus is overcome by opposing force created by shockwaves. Stone fragmentation occurs by several mechanisms.

Shock Waves composed of positive compressive waves and negative tensile waves.



Stone fragmentation varies according to stone composition cystine stones are most ESWL resistant. Next are Brushite, and Calcium Oxalate Monohydrate. Pre treatment determination of stone composition and an ability to predict the probability of fragmentation can reduce the number of fruitless shockwaves and reduce the overall cost of stone management.

Different techniques have been used to assist in determining the chemical composition of urinary calculi in vivo. Such tests include pH, identifying characterizing urinary crystals. The presence of urea splitting organisms, bone densitometry and radiographic studies.

Roentgenography has played a major role in the diagnosis and management of calculus disease. Various researchers have attempted to predict the stone composition by different methods.

Dretler pioneered the work on stone fragility and the magnitude of response of a calculus to stone fragmentation techniques. The author chooses 6 calculi with near 100% purity. These were photographed on high resolution roentgenographic paper to compare the crystal structure and allow appreciation of differences in their structure. Small spalls are noted in the calcium oxalate dehydrate COD stone. Whereas the appearance of calcium oxalate monohydrate and Brushite stones are more uniformly dense. Struvite calculi show alternating lines of dense and less opaque material. Cystine and uric acid calculi have more homogenous structure, without obvious striations. They concluded that except of cystine calculi radiologic density correlated well with stone fragility (22).

In 1996 ***Dretler and Kolt*** (23) further analyzed radiographic patterns of calcium oxalate dihydrate and monohydrate stones. Smooth edge, denser than bone, homogenous are pure calcium oxalate monohydrate stones. Radial striations and superimposed stippling pattern in calcium oxalate dihydrate stones. This study is the first proof that radiographic morphology can be related to ESWL stone free rate.

Bone et al (7) demonstrated that a smooth, denser than bone calcium oxalate monohydrate stone, fragments less efficiently than rough less dense calcium oxalate dihydrate stone.

Plain radiographs have many limitations. For distinct outline of the renal stone it should be of more than 1cm size. Moreover the stone may get masked by overlying bowel gas and for obvious appearance it should be located in an area away from bony structures.

Cohen et al showed that an accurate diagnosis of stone composition could be made by an analysis of crystals in post ESWL urine specimen using scanning Electron Microscopy and X-ray energy dispersive spectroscopy (XES) then his associates extended the use of these techniques to include examination of pre treatment urine specimen, and thereby predicting the response to ESWL success. The disadvantage of this method include unavailability of a Electron Microscopic urine examination and difficulty in predicting the nature of calculi in patients with mixed stones.

Cher Saw et al studied the ability of stone density on non contrast CT to predict the number of shock waves required for fragmentation of stones.

CT 120 KV 80mA 3mm Collimation)

The number of shock waves required for fragmentation to less than 3mm was taken as the end point. However due to technical defect of volume averaging with 3mm collimation the correlation was not due to radiological density but rather solely to stone size. They concluded that the size and not HU which determined the number of shockwaves required for fragmentation.

CT Scan is a relatively simple and non invasive technique that is available in most medical centres. Radio opaque and radiolucent calculi can be detected. Several reports have indicated that with the use of modern instrumentation uric acid and poorly mineralized matrix stones can be identified with certainty.

Hillman and his associate sought to determine the feasibility of using CT to analyse the chemical composition of renal calculi. He concluded that uric acid stone can be differentiated clearly from struvite and calcium oxalate calculi.

(CT number (or) Hounsfield unit is calculated using the formula).

$$\frac{1000 \text{ x } \mu\text{tissue -- } \mu \text{ water}}{\mu \text{ Water}}$$

μ - absorption coefficient in kilovoltage. This number is named in honor of Godfrey Hounsfield the inventor of CT Scanning when HUs are used air has a value of – 1000, water- 0 and dense bone and calcification $\geq$ + 1000.

Federle et al (30) evaluated 9 Patients and analysed CT HU with stone composition. In this study 1 uric acid stone has an attenuation value between 346-400 HU, Xanthine stone had a value of 391 HU, cystine stone 586 HU, calcium oxalate 500-1000 HU.

Kuwahara et al (31) studied the attenuation value of CT of 50 calculi more than 1cm in diameter to determine its composition. The attenuation of various calculi were measured in HU in 5mm collimation in the region of interest. Values obtained as follows. Mixed calcium oxalate Phosphate 1555±193, Magnesium Ammonium Phosphate 1285±284, calcium oxalate 1690, Calcium Phosphate 1440, Cystine 757±114. Uric acid 480. They concluded that attenuation values ranging from 500-1600 overlapped for various calculi. However uric acid calculi had attenuation value less than 500 and oxalate calculi >1000. They could not find any correlation between the attenuation value and the mineral content.

Indications

The current options available for the treatment of renal and ureteral calculi include conservative management (watchful waiting for spontaneous passage), extracorporeal shockwave lithotripsy (ESWL), endoscopic techniques (rigid or flexible ureteroscopic lithotripsy), and percutaneous treatments.

The American Urological Association Stone Guidelines Panel has classified ESWL as a potential first-line treatment for ureteral and renal stones smaller than 2 cm.

Indications for ESWL include the following:

- Individuals who work in professions in which unexpected symptoms of stone passage may prompt dangerous situations (eg, pilots, military personnel, physicians) In such individuals, definitive management is preferred to prevent adverse outcomes.

- Individuals with solitary kidneys in whom attempted conservative management and spontaneous passage of the stone may lead to an anuric state.

- Patients with hypertension, diabetes, or other medical conditions that predispose to renal insufficiency.

Contraindications

Absolute contraindications to extracorporeal shockwave lithotripsy (ESWL) include the following:

- Acute urinary tract infection or urosepsis
- Uncorrected bleeding disorders or coagulopathies
- Pregnancy
- Uncorrected obstruction distal to the stone

Relative contraindications include the following:

- Body habitus: Morbid obesity and orthopedic or spinal deformities may complicate or prevent proper positioning. In these situations, attempting to position the patient prior to anesthetic induction is useful to ensure the practicality of the approach.

- Renal ectopy or malformations (eg, horseshoe kidneys and pelvic kidneys)

- Complex intrarenal drainage (eg, infundibular stenosis)

- Poorly controlled hypertension (due to increased bleeding risk)

- Gastrointestinal disorders: In rare cases, these may be exacerbated after ESWL treatment.

- Renal insufficiency: Stone-free rates in patients with renal insufficiency (57%) (serum creatinine level of 2–2.9 mg/dL) were significantly lower than in patients with better renal function (66%) (serum creatinine level <2 mg/dL).

Preexisting pulmonary and cardiac problems are not contraindications, provided they are appropriately addressed both preoperatively and intraoperatively. In patients with a history of cardiac arrhythmias, the shockwave can be linked to electrocardiography (ECG), thus firing only on the R wave in the cardiac cycle (ie, gated lithotripsy).

Cardiac pacemakers are also not contraindicated, although seeking assistance from a cardiologist for possible changes to pacemaker settings would be prudent.

Oral anticoagulants (eg, clopidogrel [Plavix] and warfarin [Coumadin]) should be discontinued to allow normalization of clotting parameters. Platelet function is normalized by discontinuing aspirin-containing products and nonsteroidal anti-inflammatory drugs (NSAIDs) 7 days before treatment.

AIM AND OBJECTIVES

- To compare the efficacy of localization and fragmentation of renal stone by USG and fluoroscopy in ESWL based on

1. Location
2. Size
3. Mean distance between skin and stone (Morbid Obesity)
4. Radiolucency
5. Anatomic factors
6. Stent Placement

MATERIALS AND METHODS

STUDY DESIGN

This is a prospective study conducted in 110 patients of renal stone disease Based on ESWL done in department of urology, Govt. Royapettah Hospital and KMC Hospital, Chennai during the period January 2009 – January 2010.

INCLUSION CRITERIA

1. Patients with Renal stone 5mm – 2 cm in diameter in upper, middle calyx or Renal Pelvis and ≤ 1cm in lower calyx. Not an previously treated for the same.

2. All stone located in a satisfactory functioning non obstructed Renal unit.

EXCLUSION CRITERIA

- Pediatric patients
- Bleeding diathesis
- Pregnant females
- Uncontrolled infection
- Ureteric calculi
- Distal obstruction
- Congenital Anomalies
- Patients with cardiac pacemaker
- Lower calyceal stone with unfavourable anatomy.

Limiting factor

Passing debris instead of stone Bits after/ during SWL.

Totally 110 cases were taken out of which 10 cases were eliminated because of previous surgery, co-morbid illness, old age, 100 cases were selected.

Out of 100 cases 50 cases were allotted for USG guided ESWL and 50 cases for fluoroscopy guided ESWL.

Based on stone factor

1. Site
2. Size
3. Number

Based on Clinical factor

1. Skin – stone distance ≤ 10 cm

Based on Anatomic factors

1. Hydronephrosis
2. Lower pole
3. Solitary
4. Ectopic

In all patients History and Physical examination was done. Baseline investigations included were CBC, Urine Culture and Sensitive, X-ray KUB, USG KUB, CT – KUB.

Preprocedure DJ stenting was done for ≥1.5 cm Stone size.

Patients were explained about the study, ESWL procedure and informed consent obtained.

ESWL was done as out patients. Patient datas were recorded in proforma. All treatments were done with Dornier compact Delta II Electromagnetic Generator Machine with 9 inches HF fluoroscopy and 10 inches USG.

Selected patients were administered sedation Tramadol 8 mg IV, 10 min before procedure. Topical EMLA cream was used in some patients.

- A minimum of 500 shocks and maximum of 2500 stocks were given in each sitting.
- Intensity increased stepwise pattern
- Shock frequency was 60/ min/
- For fluoroscopic Guided ESWL stone fragmentation monitored every 100 shocks.
- For USG – continuous monitoring.

Adequate fragmentation was accepted when following were observed.

1. Alteration in stone configuration.
2. Increase in stone surface area
3. Hydronephrosis in Non- hydronephrotic Renal unit (USG Guided)
4. Obviously separated fragment
5. Decreased overall density
6. Irregularity in outline.

Patients counseled about the procedure and explained about sedation effects, pain, haematuria and voiding of fragments and possible success rate and need for second sitting / treatment.

After each session of treatment patients were observed for 2-3 hours period & allowed to go home.

Antibiotics, Analgesics and fluid intake of 3-5 l/day along with potassium citrate syrup adviced.

All patients were instructed to pass urine through sieve (coffee filter) and to collect stone fragments. This was brought to us in follow up for chemical analysis.

Post procedure follow-up

Patients followed up at 2 weeks with x-ray KUB, USG KUB and selected CT KUB in fluoro guided ESWL.

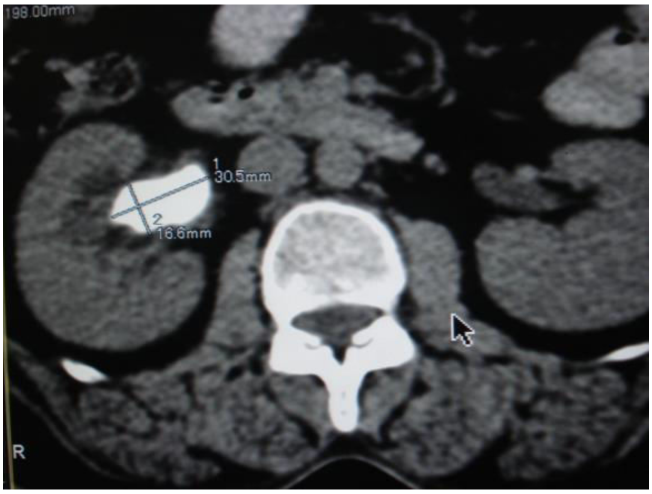
In USG Guided patients instructed about the fragmentation, stone clearance in patients with residual fragments patients were advised for II sitting ESWL on same day.

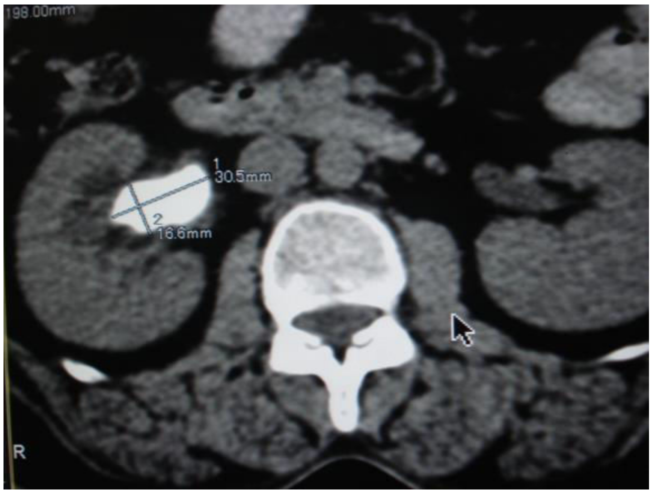
Residual calculi by X-ray, USG KUB and CT KUB < 5mm (CIRF) clinically insignificant residual fragment were considered adequately treated. Residual fragments > 5mm considered treatment failure.

The stone fragments brought by the Patients were collected, labeled and sent for chemical composition analysis, biochemistry dept, MMC (by chemical dissolution method stone composition was detected).

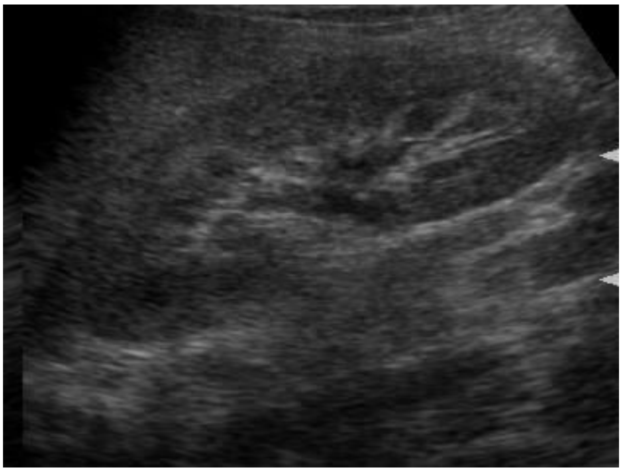
STONE FREE GROUP

PRE ESWL



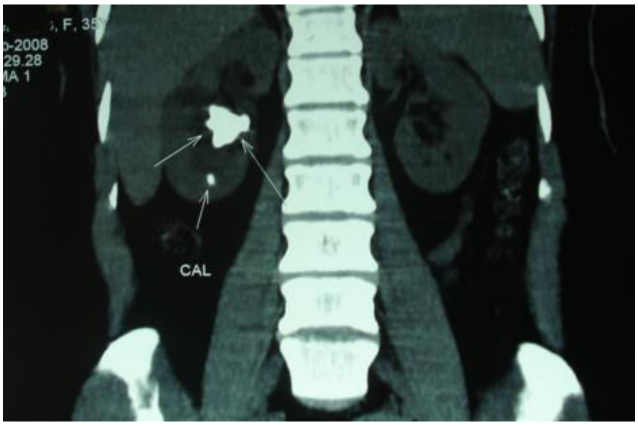


POST ESWL

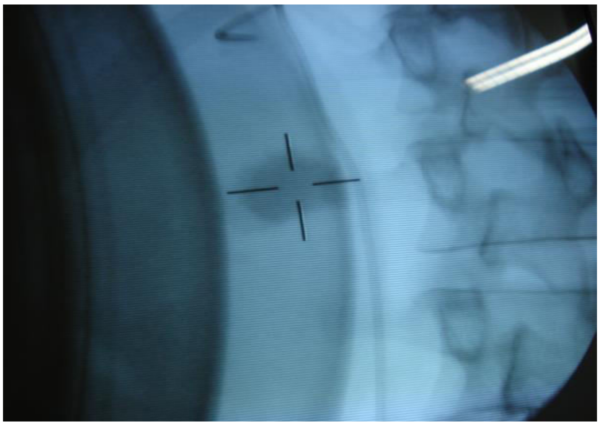


STONE FRAGMENTATION GROUP

PRE ESWL



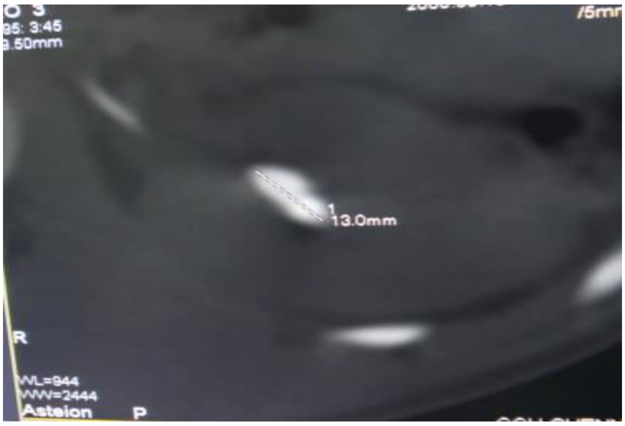
FLUORO FOCUSING

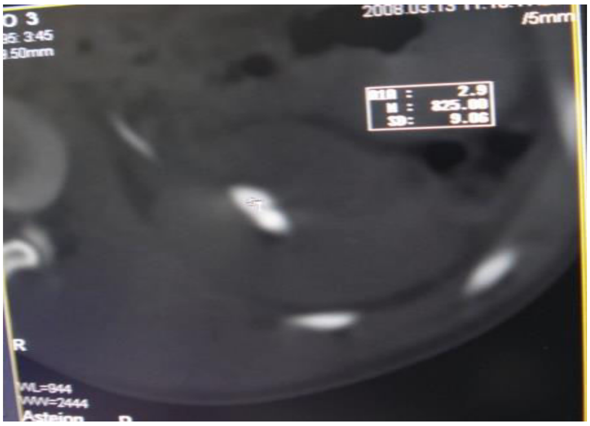


POST ESWL

STONE FRAGMENTATION GROUP

PRE ESWL

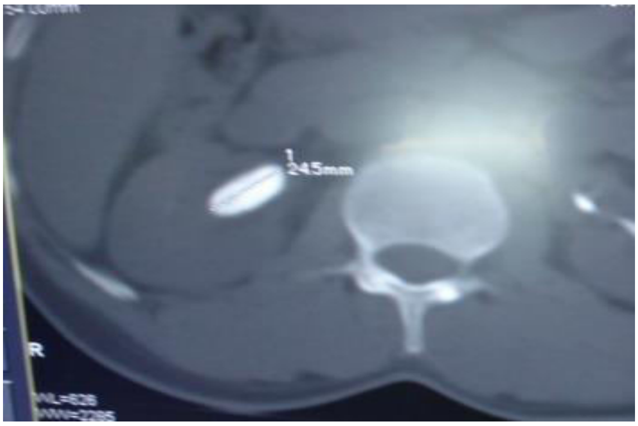




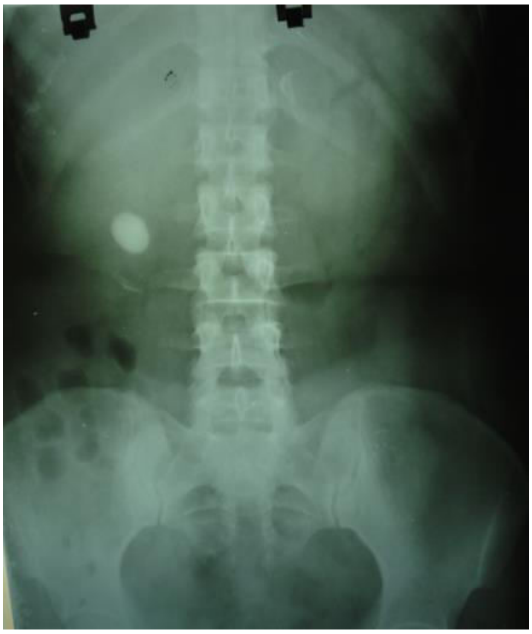
POST ESWL

STONE WITH RESIDUAL FRAGMENTS (Failure of Treatment)

PRE ESWL



POST ESWL



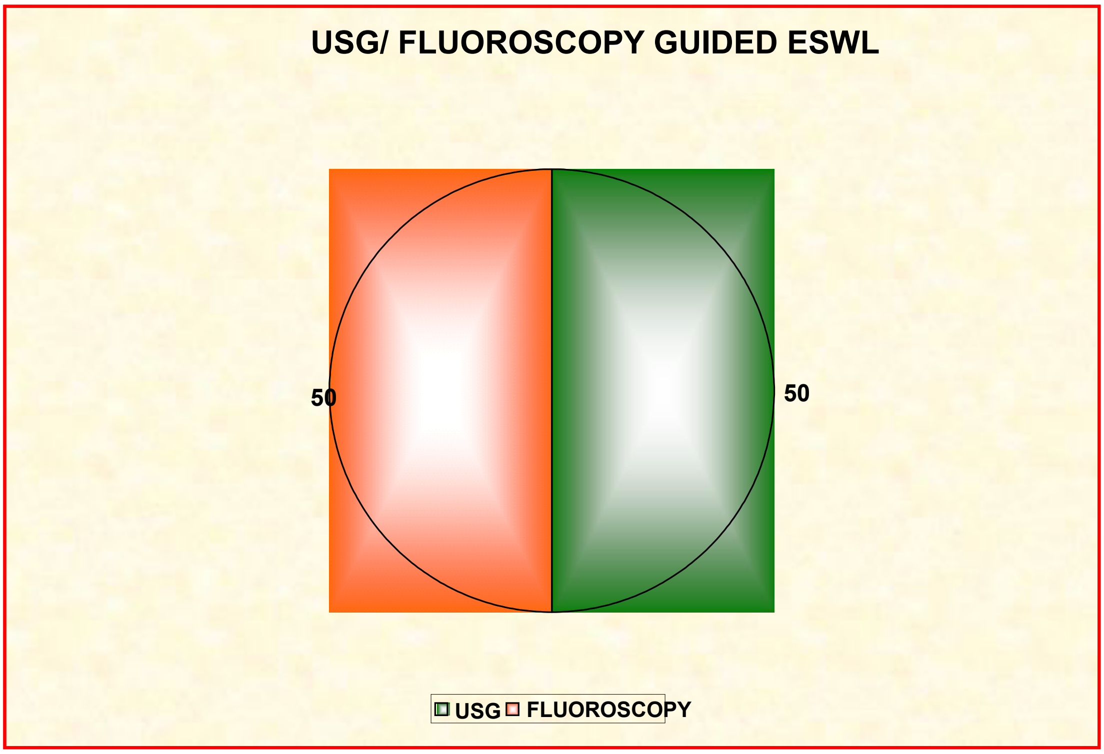
RESULTS & OBSERVATIONS

50 patients for USG guided and 50 patients for fluoro guided under went ESWL who had satisfied the inclusion and exclusion criteria mentioned earlier and later underwent.

USG / Fluoroscopy guided ESWL

Out of 100 patients 50 patients were taken for USG guided and 50 patients were taken for fluoroscopy guided study.

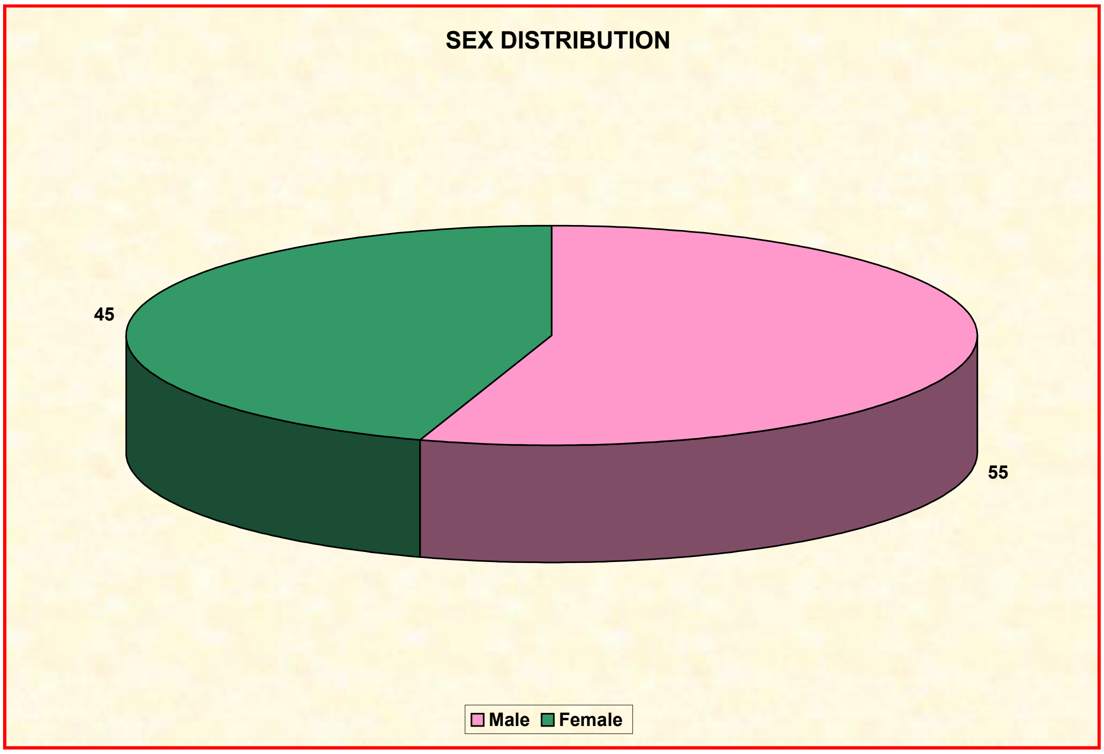
USG	Fluoroscopy
50	50



SEX DISTRIBUTION

There were 55 Male Patients and 45 Female Patients in the study.

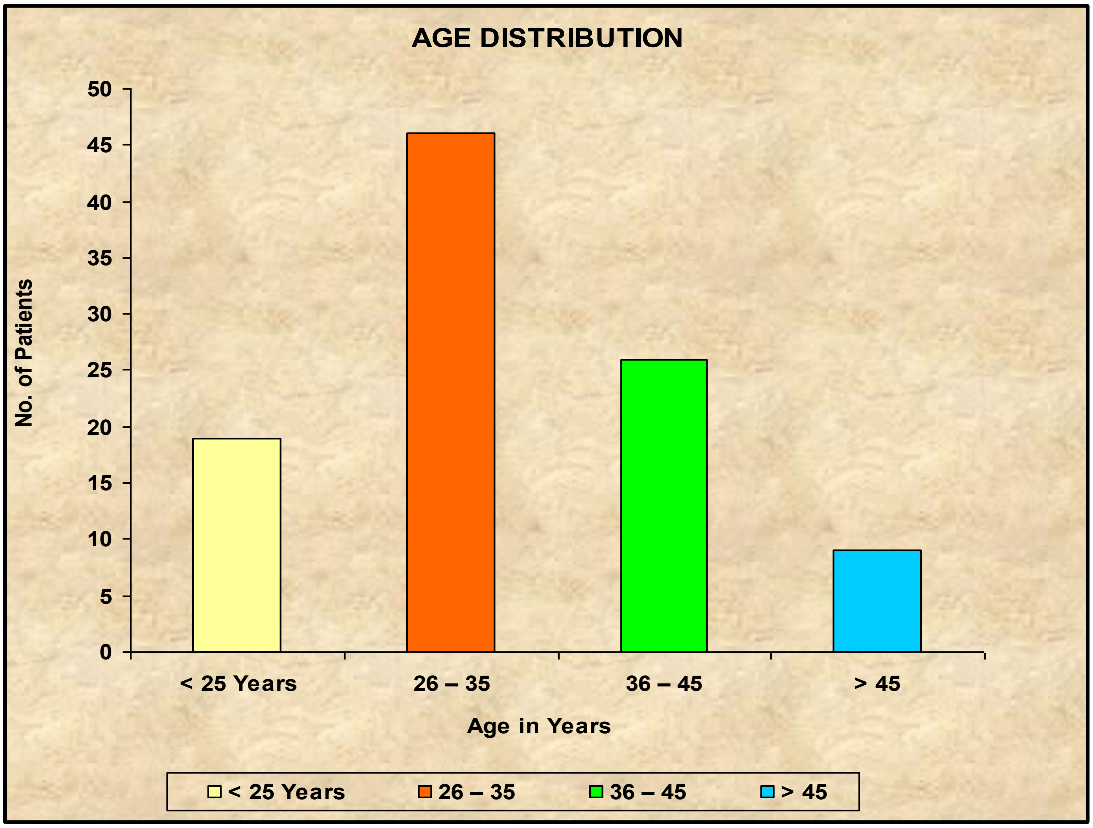
MALE	FEMALE
55	45



AGE DISTRIBUTION

No of patients according to the age ranged from below 25 years 19 patients, 26 – 35 years 46 patients, 36– 45 years 26 patients, > 45 years 9 patients.

Age	No. of Patients
< 25 Years	19
26 – 35	46
36 – 45	26
> 45	9



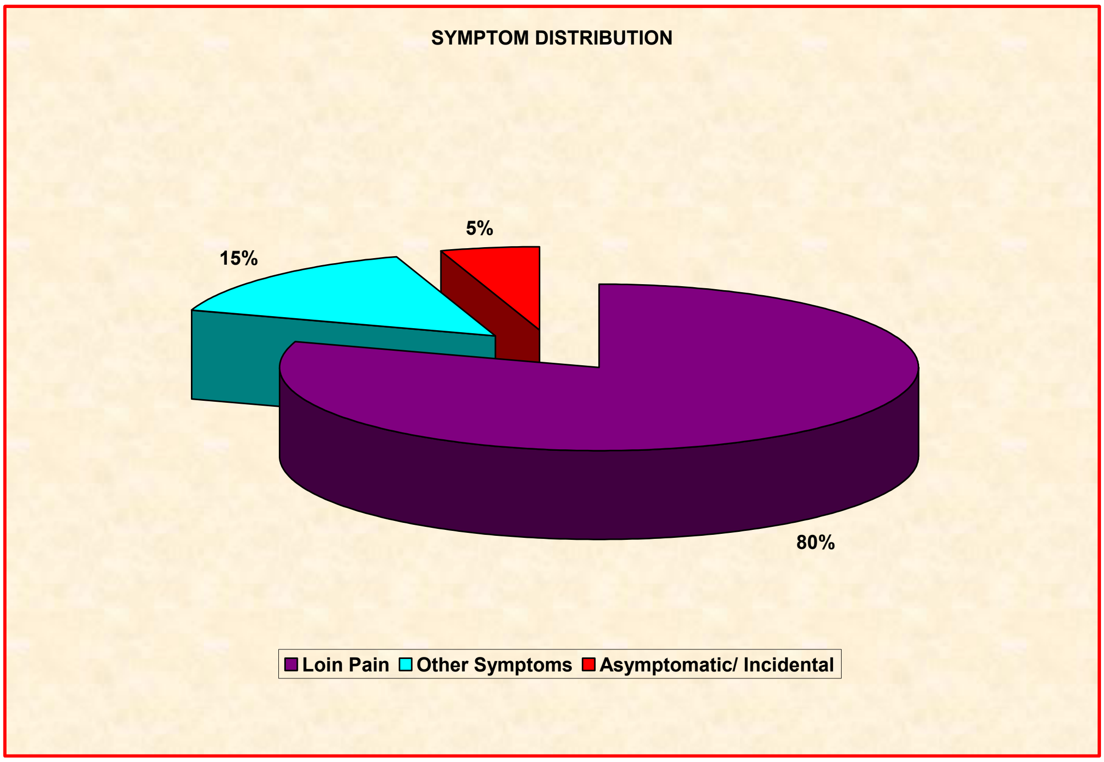
SYMPTOM DISTRIBUTION

Majority of the patients (80%) presented with loin pain with or without associated symptoms.

10-15% of the patients presented without loin pain with other symptoms like dysuria, fever, vomiting.

5% of the patients were asymptomatic and incidentally detected.

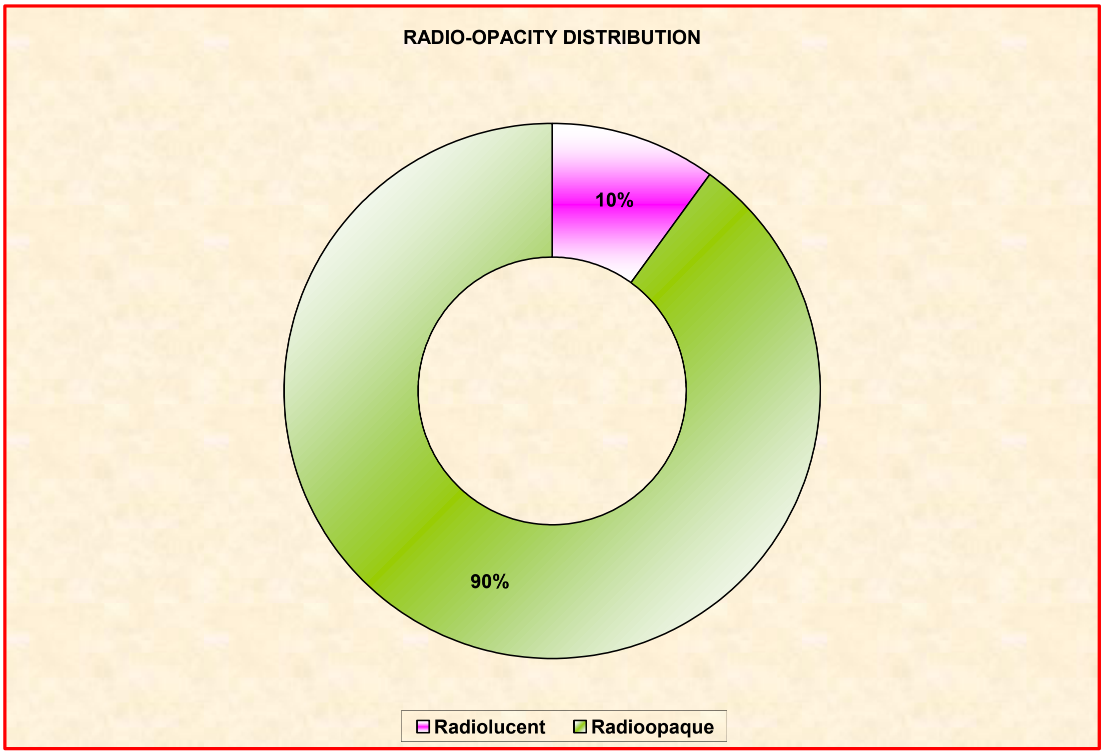
SYMPTOMS	NO. OF PATIENTS	PERCENTAGE
Loin Pain	80	80%
Other Symptoms	15	15%
Asymptomatic / Incidental	5	5%



RADIO – OPACITY DISTRIBUTION

Out of 100 patients included in the study 10% were radiolucent and 90% were Radioopaque.

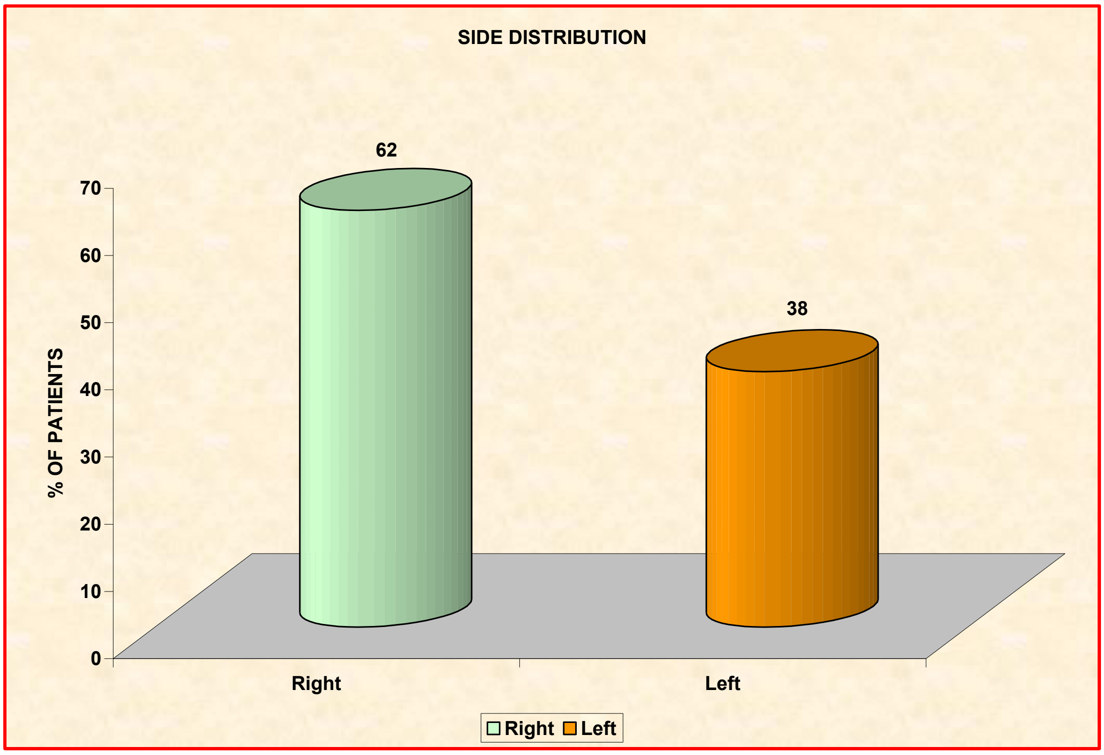
Radiolucent	Radioopaque
10	90



SIDE DISTRIBUTION

Right side stones observed in 62 patients and left side stones observed in 38 patients.

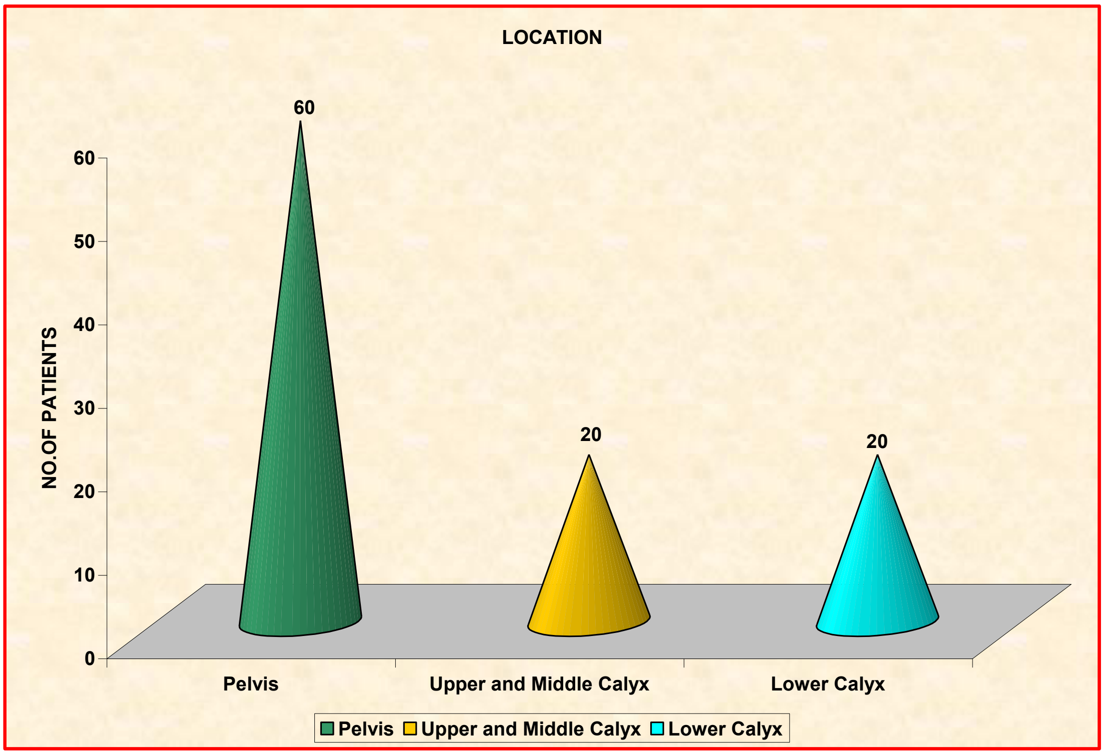
Right	Left
62	38



LOCATION

The stone distribution anatomically was as follows: 60 patients had stone in renal pelvis, 20 patients had stone in upper calyx and middle calyx and 20 patients had stone in lower calyx with favourable anatomy.

LOCATION	NO. OF PATIENTS
Pelvis	60
Upper and Middle calyx	20
Lower calyx	20

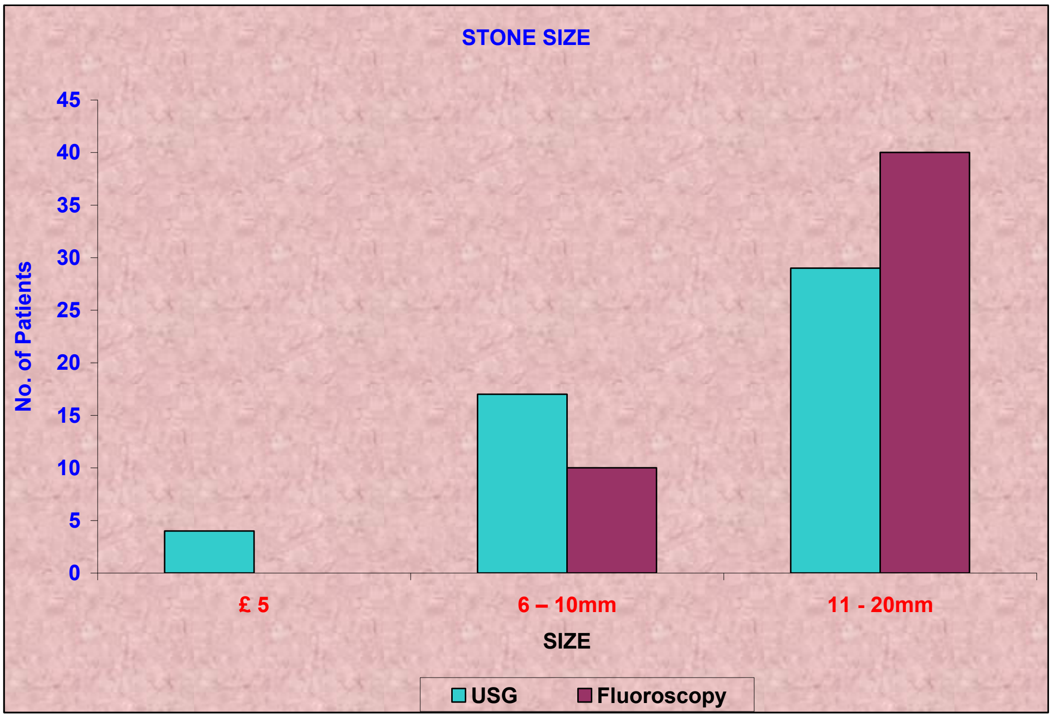


SIZE

Among the patients in USG guided group, there were 4 patients in size between $\leq$ 5mm, 17 patients in size 6 – 10mm, 29 patients in stone size > 10 mm.

Among the patients in fluoro guided group, there were 4 patients in size between 5- 10 mm 36 patients in size between 10 – 20mm 6 patients in size > 20mm.

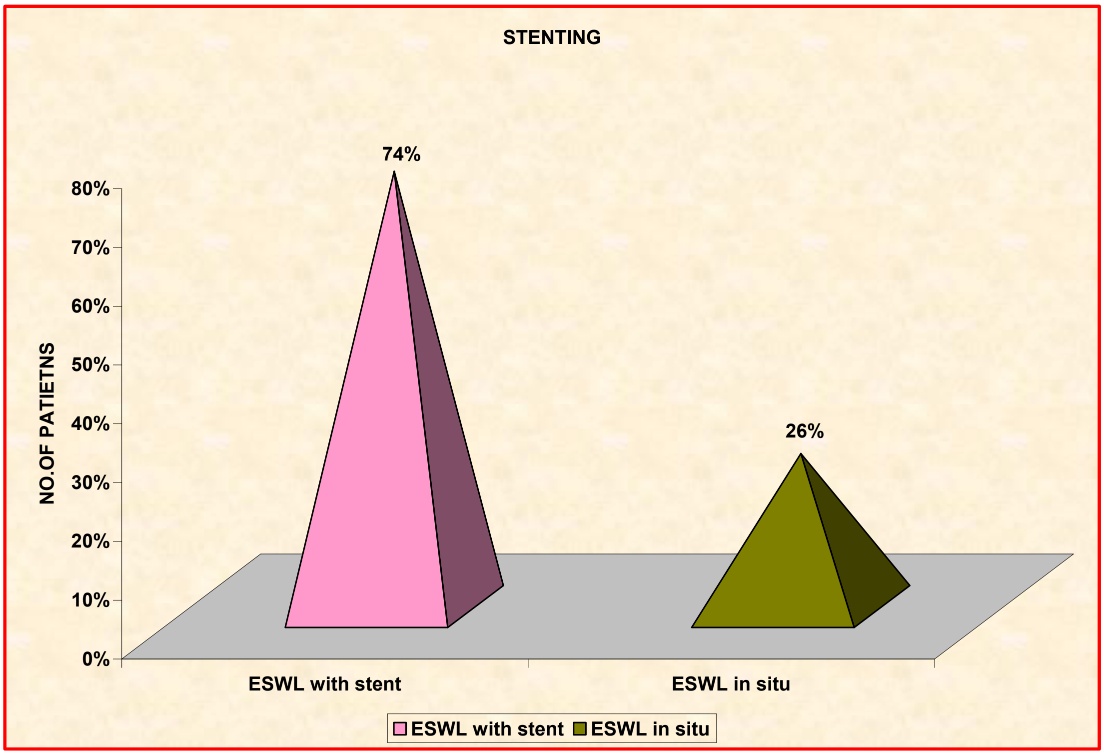
Size	USG	Fluoroscopy
$\leq$ 5	4	Nil
6 – 10mm	17	10
11 - 20mm	29	40



STENTING

Stone Size >1.5CM were stented, 74% patients were stented and 26% patients were not stented.

ESWL with stent	**ESWL in situ**
74%	26%



FRAGMENTATION AND CLEARANCE

USG GUIDED ESWL

Size mm	No. of Patients	Radi-olucent	Radio opaque	No. of Shocks	Stone Free	Frag-mented completely	Residual fragments	II ESWL	Auxiliary Proce-dures
< 5	4	2	2	500 - 1000	4	-	-	-	-
6 – 10	17	7	10	1000 - 1500	12	3	1	2	-
11- 20	29	11	18	2500 - 5000	19	8	3	2	2

FLUOROSCOPIC GUIDED ESWL

Size mm	No. of Patients	Radi-olucent	Radio opaque	No. of Shocks	Stone Free	Frag-mented completely	Residual fragments	II ESWL	Auxiliary Proce-dures
< 5	-	-	-	-	-	-	-	-	-
6 – 10	10	-	10	1500 - 2000	6	3	1	1	-
11 – 20	40	-	40	2500 - 5000	26	10	4	3	1

<u>USG Guided ESWL</u>

Out of 50 cases, both Radiolucent and Radio Opaque stones, mean distance between skin – stone < 10 cms, more kidney movement even after sedation, CIRF – clinically insignificant residual fragment were the selection criteria before placing the patient on gantry.

Out of 5 patients of < 5 mm, 2 were Radiolucent and 2 were Radio Opaque. No. of shocks ranged between 500 – 1000. All 4 patients were stone free.

Out of 17 patients of 6 – 10 mm, 7 were Radiolucent and 10 were Radio Opaque. No. of shocks ranged between 1000 – 1500. Stone free were 12 patients, complete fragmentation was 3 patients, one patient was with residual fragment. Two patients underwent II sitting ESWL.

Out of 29 patients of 11 - 20 mm, 11 were Radiolucent and 18 were Radio Opaque. No. of shocks ranged between 2500 – 5000 in single or double sitting. 19 patients were stone free. 8 were completely fragmented 3 were with residual fragments. 2 patients underwent II sitting ESWL Other two patients underwent Auxiliary procedures.

Fluoroscopy Guided ESWL

Out of 50 cases, all were Radio Opaque stones, mean distance between skin – stone > 10 cms, less kidney movement before or after sedation were the selection criteria before placing the patient on gantry.

It was very difficult to localise < 5 mm and hence these patients are not selected in this group.

Out of 10 patients of 6 – 10 mm, all were Radio Opaque. No. of shocks ranged between 1500 - 2000. Stone free were 6 patients, completely fragmented were 3 patients one patient was with residual fragment who underwent II sitting ESWL.

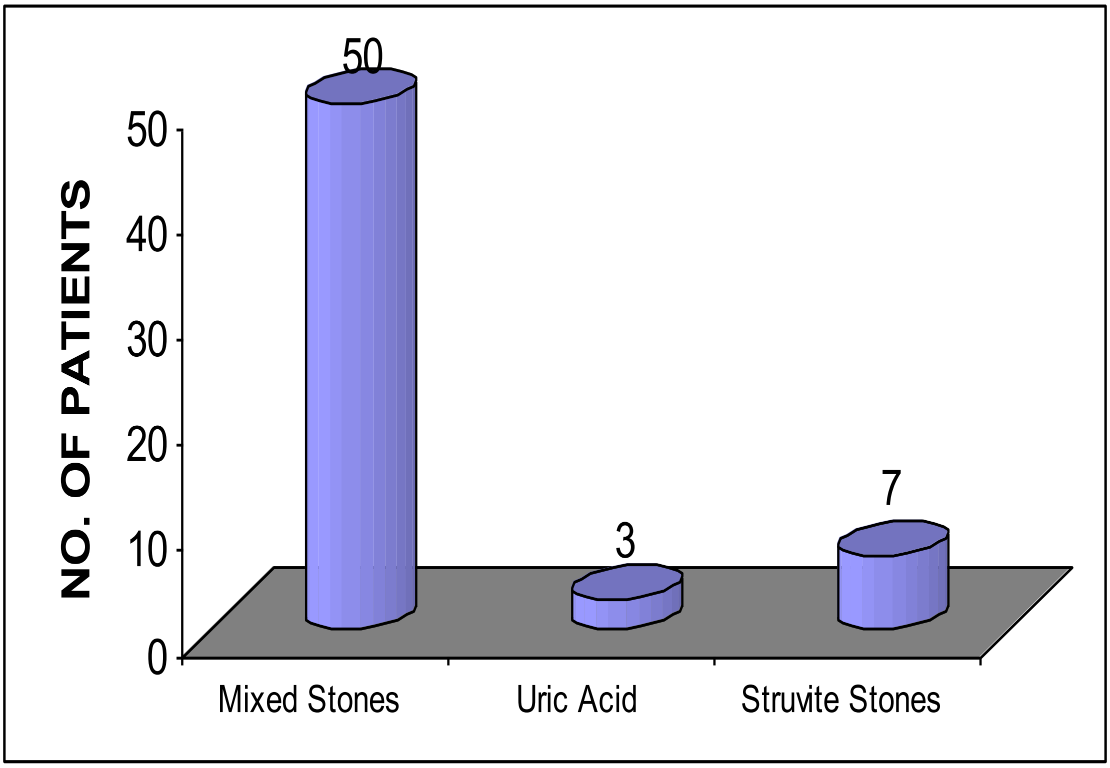
Out of 40 patients of 11 - 20 mm, No. of shocks ranged between 2500 – 5000 in single or double sitting. 26 patients were stone free. Ten patients were completely fragmented, 4 were with residual fragments 3 patients underwent II sitting ESWL. One patient underwent Auxiliary procedures.

CHEMICAL COMPOSITION

The chemical composition of post ESWL fragments was obtained in 60 patients by chemical dissolution method (qualitative analysis). The following table depicts the various chemical compositions.

40 patients were not able to retrieve their stones.

TYPE OF STONE	NO. OF PATIENTS	HU
Mixed Stones (Calcium, Oxalate, Phosphate & Uric Acid)	50	400 – 1000
Uric Acid	3	600 – 900
Struvite Stones	7	550 – 750



COMPLICATIONS

MINOR

1.	LUTS	-	50	- Conservative management
2.	Hematuria	-	10	- Conservative management
3.	Stent migration	-	2	- Re-positioning (1), removal (1)
4.	steinstrasse	-	2	- URS/ ICL / DJ stenting

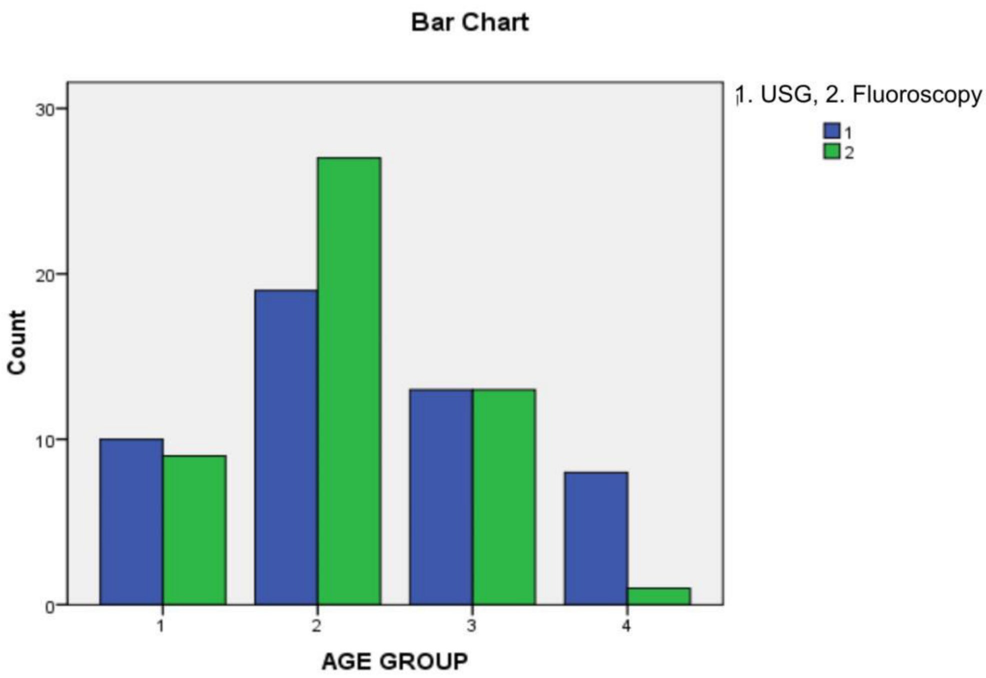
NO MAJOR COMPLICATIONS

STATISTICS

AGE GROUP * USG/FLUOROSCOPY

			Usg/Fluoroscopy		
			1	2	Total
AGE GROUP	<u><</u>25 (1)	Count	10	9	19
		% within USG/FLUOROSCOPY	20.0%	18.0%	19.0%
	26 to 35 (2)	Count	19	27	46
		% within USG/FLUOROSCOPY	38.0%	54.0%	46.0%
	36 to 45 (3)	Count	13	13	26
		% within USG/FLUOROSCOPY	26.0%	26.0%	26.0%
	46 & above (4)	Count	8	1	9
		% within USG/FLUOROSCOPY	16.0%	2.0%	9.0%
	Total	Count	50	50	100
		% within USG/FLUOROSCOPY	100.0%	100.0%	100.0%

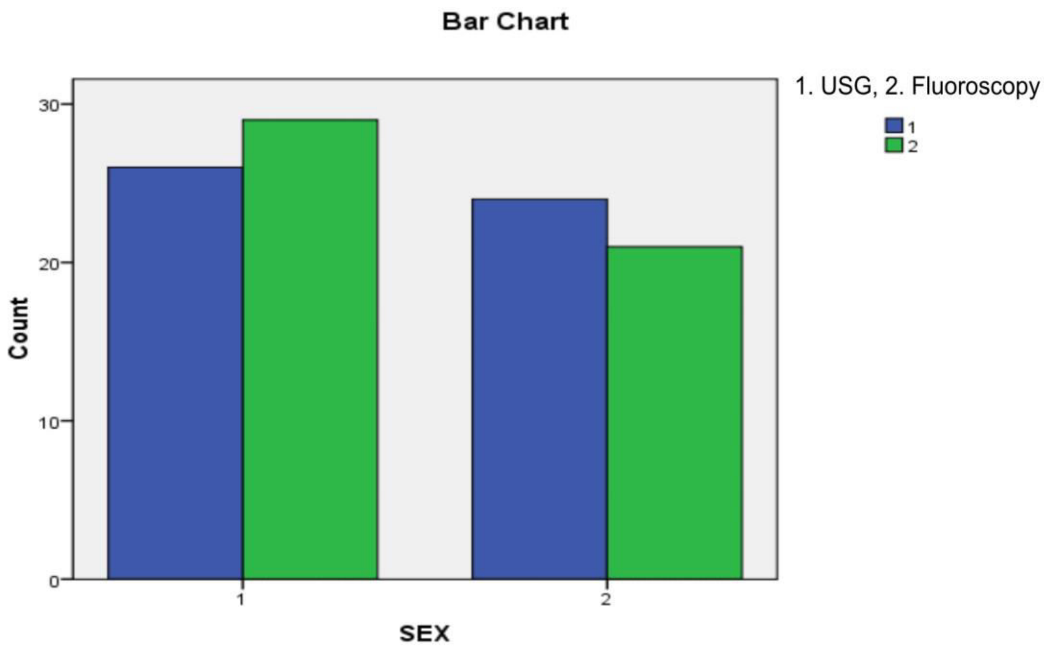
P>0.05 NOT SIGNIFICANT.



SEX * USG/FLUOROSCOPY

			USG/FLUOROSCOPY		
			1	**2**	**Total**
SEX	Male (1)	Count	26	29	55
		% within USG/FLUOROSCOPY	52.0%	58.0%	55.0%
	Fe-male (2)	Count	24	21	45
		% within USG/FLUOROSCOPY	48.0%	42.0%	45.0%
	Total	Count	50	50	100
		% within USG/FLUOROSCOPY	100.0%	100.0%	100.0%

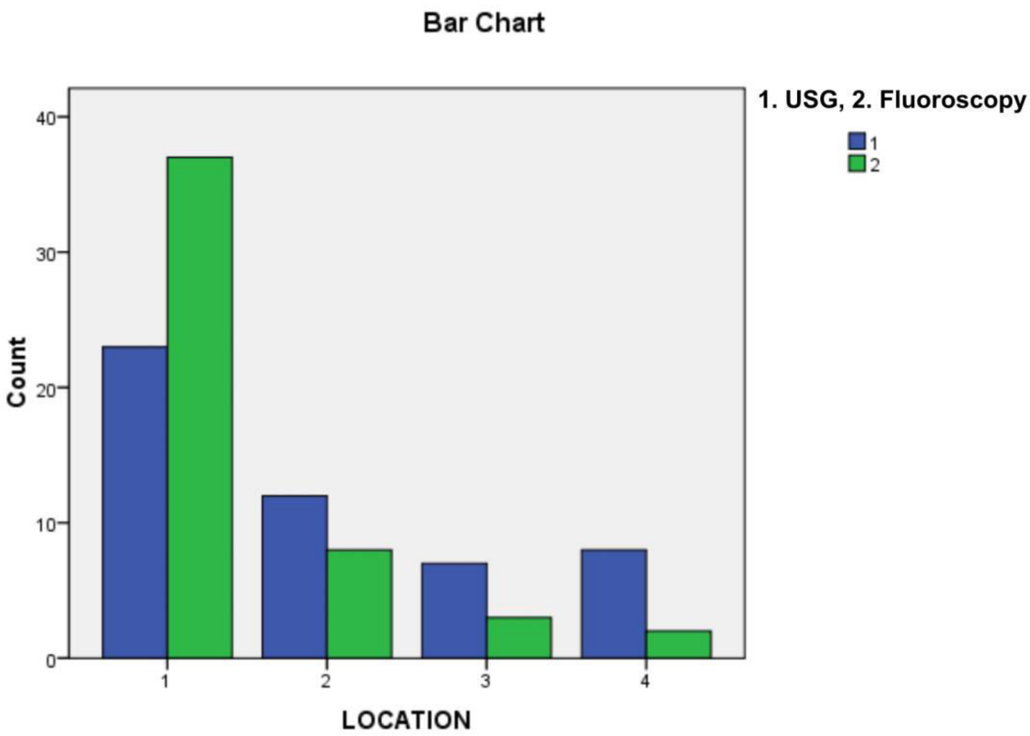
P=0.546 NOT SIGNIFICANT.



LOCATION * USG/FLUOROSCOPY

			USG/FLUOROSCOPY		
			1	2	Total
Location	1 (Renal pelvis)	Count	23	37	60
		% within USG / FLUOROSCOPY	46.0%	74.0%	60.0%
	2 (Lower calyx)	Count	12	8	20
		% within USG / FLUOROSCOPY	24.0%	16.0%	20.0%
	3 (Middle calyx)	Count	7	3	10
		% within USG / FLUOROSCOPY	14.0%	6.0%	10.0%
	4 (Upper calyx)	Count	8	2	10
		% within USG/ FLUOROSCOPY	16.0%	4.0%	10.0%
	Total	Count	50	50	100
		% within USG/ FLUOROS COPY	100.0%	100.0%	100.0%

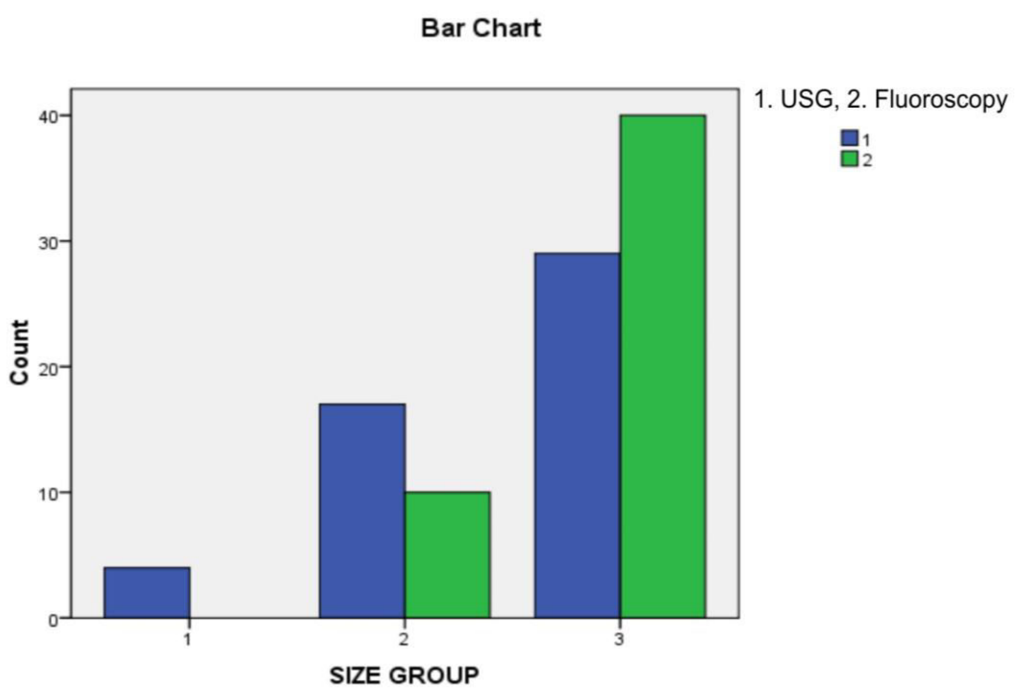
P=0.026 SIGNIFICANT.



SIZE * USG/ Fluoroscopy

			USG/FLUOROSCOPY		
			1	2	Total
SIZE GROUP mm	1 (≤ 5)	Count	4	0	4
		% within USG/FLUOROSCOPY	8.0%	.0%	4.0%
	2 (6–10)	Count	17	10	27
		% within USG/FLUOROSCOPY	34.0%	20.0%	27.0%
	3 (10– 20)	Count	29	40	69
		% within USG/FLUOROSCOPY	58.0%	80.0%	69.0%
	Total	Count	50	50	100
		% within USG/FLUOROSCOPY	100.0%	100.0%	100.0%

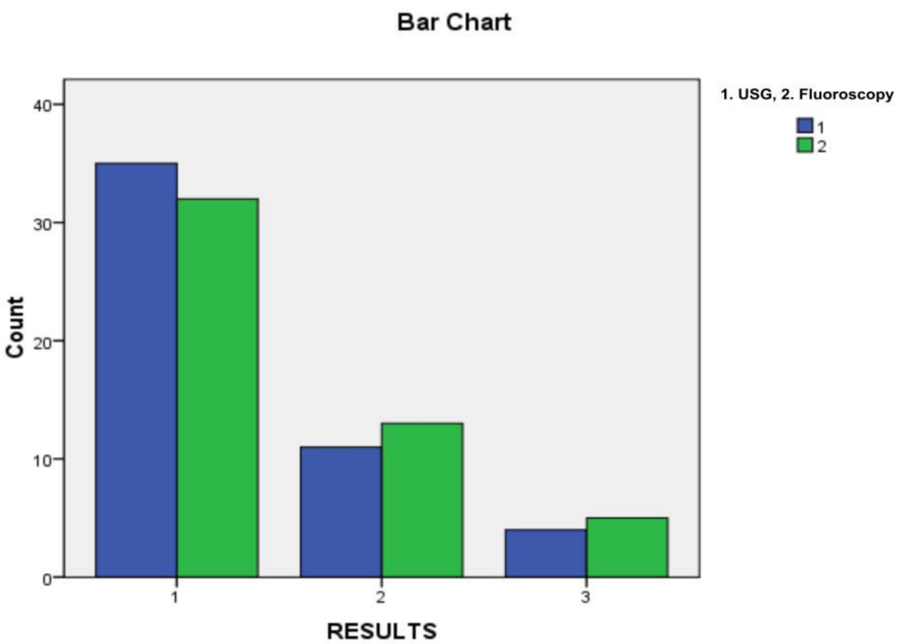
P=0.023 SIGNIFICANT.



RESULTS - FRAGMENTATION * USG/FLUOROSCOPY

			USG / FLUOROSCOPY		
			1	**2**	**Total**
Results	1 (stone free)	Count	35	32	67
		% within USG/FLUOROSCOPY	70.0%	64.0%	67.0%
	2 (completely fragmented)	Count	11	13	24
		% within USG/FLUOROSCOPY	22.0%	26.0%	24.0%
	3 (residual fragment)	Count	4	5	9
		% within USG/FLUOROSCOPY	8.0%	10.0%	9.0%
	Total	Count	50	50	100
		% within USG/FLUOROSCOPY	100.0%	100.0%	100.0%

P=0.814 NOT SIGNIFICANT,



T-Test

Group Statistics

	USG / FLUOROSCOPY	N	Mean	Std. Deviation	Std. Error Mean
AGE	1	50	34.74	9.852	1.393
	2	50	31.32	6.841	0.967

Group Statistics

	USG / FLUOROSCOPY	N	Mean	Std. Deviation	Std. Error Mean
SIZE mm	1	50	12.24	4.250	.601
	2	50	14.04	3.386	.479

P=0.021 SIGNIFICANT

Group Statistics

	USG / FLUOROSCOPY	N	Mean	Std. Deviation	Std. Error Mean
NUMBER OF SHOCKS	1	50	2134.50	956.201	135.227
	2	50	2552.00	585.352	82.781

P=0.010 SIGNIFICANT

There exists a statistical significant difference between the USG and fluoroscopy group with respect to shocks given to respected patients. The mean level of number of shocks for USG- group is 2134.50 which is less than fluoroscopy group.

Group Statistics

	USG / FLUOROSCOPY	N	Mean	Std. Deviation	Std. Error Mean
CTHU	1	50	726.40	161.886	22.894
	2	50	727.20	115.935	16.396

P=0.977 NOT SIGNIFICANT

DISCUSSION

ESWL has revolutionized the treatment strategy of urolithiasis world wide and continue to be a major therapeutic modality for treating the majority of upper urinary tract stones. It's non invasive nature along with high efficacy has resulted in outstanding patient and surgeon acceptance.

ESWL is the preferred modality of treatment for renal stones less than 2 cm. However stone free rate (SFR) after treatment had never been near 100% and in our study it has between the range of 65 – 75 %.

The success rate of ESWL is determined by factors such as stone factors, clinical factors and anatomic factors. Fragility dependent factors are size, composition and density of stone.

Regarding size of the stone, **approximately 50 – 60 % of all Solitary Renal Calculi are less than 10 mm in diameter. (Cass 1995, Renner & Rassweiler 199, Logarakis et. al 2000).** Treatment result of SWL for this substantial group of patients are generally satisfactory and independent of stone location and composition. In our study CIRF < 5mm are better localised by USG and stone clearance is easily achieved with minimum number of shocks in short duration with out sedation. Stone free % in this group was almost 100 % in one study.

In our study Patients with calculi between 5 – 10mm, both USG and Fluoroscopy localization were almost with same stone free results. Reduced number of shocks by USG Guided was because of its continuous monitoring & frequent adjustment of probe position.

Patients with **10 – 20** mm are often treated with SWL as first line of management. Stone composition and location also affect the result of ESWL for this group of size. In our study the results of USG vs fluoroscopy factors influencing the fragmentation and number of shocks were obesity, stone–skin mean distance, movement of kidney, radiolucency, stent, hydronephrosis. Only in selected patients NCCT was done and the HU were within 1000.

Morbid obesity, defined as >100 pounds overweight. >200% of ideal bodyweight, or body mass index [a value obtained by weight in kg divided by height in meters square] greater then 40 posses a number of physiological technical challenges to the successful treatment of kidney stones **[Geblin et al 1995; Fredmen et al 2002].** Factors based on morbid obesity are weight limitation on lithotripter table or gantry, inability to target stone radiographically or skin to stone distance that exceeds the maximum allowable focal distance of the lithotripter. Machine with greatest focal length and highest peak pressure should be selected **(Hofmann and Stoller 1992).** In our study the selection of obesity was based on <10 cm placed under USG and >10cm under fluoroscopy guided. Localisation and targeting was better by fluoroscopy when distance was more. But lesser the distance, good localization with continuous monitoring gave quicker results with lesser number of shocks in USG guided group.

Radiation hazard is a main factor for USG guided ESWL nowadays. Radiation hazard is not only for the patient but also for the consultant and technician. Health hazard is calculated from the formula $1/d^2$.

Rib is another factor for localization because of more kidney movement with long rib. In our study USG guided was useful by frequent change in focal point there by reducing the waste shocks on ribs.

Hydronephrosis is prerequisite for PCNL but a negative factor for ESWL. In our study calculus with pelviectasis or calyectasis led to frequent change in focal point and continuous monitoring reduced the number of shocks with early fragmentation.

Stone composition- Dretller (1988) first introduced concept of stone fragility. **Teichman and collegues (1998b)** reported that holmium laser in vitro was the most effective lithotrite for fragmenting struvite stone and least effective lithotrite for calcium oxalate monohydrate stones. **Saw and Lingeman (1999)** reported that adjusted for size,cystine and brushite calculi are the most resistant to SWL followed by calcium oxalate monohydrate following in descending order of resistance to fragmentation are struvite, calcium oxalate dehydrate and uric acid stones **(Pittomvils et al, 1994; Sand Lingeman 1999).**

In our study post ESWL fragments was obtained in 60 patients by **chemical dissolution** method. In our study we found complete fragmentation of uric acid and struvite stones in the first sitting.

CONCLUSION

USG Guided ESWL is preferred option in all renal calculus. $<$ 2 cm in renal pelvis, upper calyx and middle calyx, $\leq$ 1 cm in lower calyx. It is a most preferred option in other following conditions like.

1. Clinically insignificant Residual fragment
2. Paediatric groups.
3. Solitary Kidney
4. Radiolucent stone
5. Skin to stone mean distance $\leq$ 10 cm.
6. Because of radiation hazard.

In all group of patient No. of shocks is comparatively is less when compared to fluoroscopic guided ESWL.

Fluoroscopy guided ESWL in renal calculus is a preferred option when it is difficult to localize by USG, Morbid obesity (Skin – stone distance $\geq$ 10 cm in our study.

Both ultra sound and fluoroscopic guided ESWL has its own advantages and dis-advantages.

Wherever USG guided ESWL is available it is the most preferred option.

Wherever Fluoroscopy guided ESWL is available USG as a combined modality is an added advantage.

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